



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

September 3, 2002

Nicholas Tantillo
Barr Laboratories, Inc.
2 Quaker Road
P.O. Box 2900
Pomona, NY 10970-0519

Dear Mr. Tantillo:

Your petition requesting the Food and Drug Administration to determine whether Ortho-Tri-Cyclen-21 tablets, NDA 19 697, has been voluntarily discontinued for reasons of safety or effectiveness, was received by this office on 09/03/02. It was assigned docket number 02P-0392/CP 1 and it was filed on 09/03/02. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,


Gloria Ortega
Dockets Management Branch

02P.0392

ACK 1